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222, 224, 226, and 228. Accordingly, upon entry of this Amendment, claims 209, 214, 218-220 and 222-228 as amended will be pending and under examination.

Applicants maintain that this Amendment raises no issue of new matter and is fully supported by the specification as filed. Applicants have amended the specification and claims 224 and 226 to capitalize the word "FLAG" as required by the Examiner and to include the "®" symbol. Support for the amendments to claim 222 may be found inter alia in the specification, as originally-filed, on page 38, lines 14-17; page 39, lines 14-17; page 40, lines 1-4; page 42, lines 11-14; page 45, lines 28-33; page 66, line 8 through page 67, line 2; and page 68, line 22 through page 69, line 24. Support for the amendment to claim 226 may be found inter alia in the specification, as originally-filed, on page 38, lines 19-31. Support for the amendment to claim 228 may be found inter alia in the specification, as originally-filed, on page 45, lines 1-5.

Accordingly, applicants respectfully request that the Amendment be entered.

#### Claim Objections

On page 3 of the November 6, 2001 Office Action the Examiner stated that claims 226 and 228 are objected to because of informalities found in section (b) of both claims, namely, the first and second sub-sections are labeled (iii) and (iv) or (v) and (vi), and there are no sub-sections (i) and (ii) and/or (iii) and (iv) before them.

The Examiner further objected to claim 228 because the word "contracting" on the first line of section (2) should be "contacting".

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In response, applicants have amended claims 226 and 228 to correct the enumeration of sub-sections of (b) in both claims. Applicants have further amended claim 228 to correct the spelling error mentioned hereinabove. In view of the amendments and remarks made hereinabove, applicants respectfully request that these objections be withdrawn.

Rejections Under 35 U.S.C. § 112, First Paragraph

a. On page 3 of the November 6, 2001 Office Action the Examiner rejected claims 222 and 223 under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner alleged that claims 222 and 223 encompass a method of obtaining a composition which comprises admixing a carrier and a chemical compound...or a novel structural and functional analog or homolog thereof. The Examiner alleged that there is no disclosure in the specification of what a structural and functional analog or homolog of such a compound would be, and is therefore new matter.

In response, applicants respectfully direct the Examiner's attention to the definitions of analog and homolog recited in Dorland's Illustrated Medical Dictionary, 24<sup>th</sup> Edition, 1965. Analog is defined as "[a] chemical compound with a structure similar to that of another but differing from it in respect to a certain component...", while homolog is defined as "[i]n chemistry, one of a series of compounds, each of which is formed from the one before it by the addition of a constant element." Applicants attach hereto as **Exhibit B** copies of the relevant

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pages from Dorland's Illustrated Medical Dictionary. Applicants note that claim 223 does not recite "homolog" or "analog".

Applicants maintain that a radiolabeled homolog and analog of a compound that binds hOb-Re, i.e. [<sup>125</sup>I]leptin, is disclosed in the specification on page 17, line 23 through page 18, line 36. Applicants further maintain that leptin homologs and analogs were well-known in the art at the time the application was filed, as evidenced by PCT International Publication No. WO 96/05309 referenced on page 75, line 37 of the specification as originally filed, and attached hereto as **Exhibit C**. (See, for example, page 36, line 25 through page 41, line 11; and page 43, line 3 through page 46, line 13 of PCT International Publication No. WO 96/05309.) Applicants point out that the disclosure of PCT International Publication No. WO 96/05309 has been incorporated by reference into the subject application. See page 1, lines 6-11, of the instant specification which recites:

Throughout this application various references are referred to within parentheses. Disclosures of these publications in their entireties are hereby incorporated by reference into this application to more fully describe the state of the art to which this invention pertains.

Applicants maintain that one skilled in the art would know what a structural and functional homolog or analog of such a compound would be due to the many examples of such compounds available to the skilled artisan at the time the application was filed. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

b. On page 4 of the November 6, 2001 Office Action the Examiner further rejected claims 222 and 223 under 35 U.S.C. §112, first

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paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner alleged that claims 222 and 223 are rejected for reciting the step "wherein said chemical compound has been recovered free of any soluble polypeptide". The Examiner alleged that there is no disclosure in the specification of this step, and is therefore new matter.

In response, in an attempt to advance the prosecution of the subject application, but without conceding the correctness of the Examiner's position, applicants have amended claim 222 to recite:

The method of obtaining a composition which comprises:

- (a) identifying a chemical compound by the process of any of claims 224, 209, 225, 226, 214 or 227, or a structural and functional analog or homolog thereof,
- (b) recovering said chemical compound free of any soluble polypeptide, and
- (c) admixing a carrier and a pharmaceutically effective amount of said chemical compound.

Applicants point out that claim 223 is dependent on claim 222. Applicants maintain that the "recovery step" recited in claim 222 is supported in the specification as originally filed on page 66, lines 30-32; and page 69, lines 11-14. Applicants maintain that the instant specification's disclosure of assays, such as radioligand binding (page 66, line 8 through page 67, line 2) and phosphoinositide metabolism (page 68, line 22 through page 69,

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line 24), clearly outline a step in which the reaction mixture is filtered or separated, thus recovering the compound free of any receptor.

In light of the amendments and remarks made hereinabove, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

**Rejections under 35 U.S.C. §112, second paragraph**

On page 4 of the November 6, 2001 Office Action, the Examiner rejected claims 208, 213, 214, 226 and 227 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

a. The Examiner rejected claim 208 under 35 U.S.C. §112, second paragraph, as allegedly vague and indefinite, because it is dependent on claim 224, which is a method for determining whether a chemical compound specifically binds to a soluble polypeptide. The Examiner then stated that the detection method in claim 208 comprises detecting binding of an antibody to the soluble polypeptide. The Examiner alleged that it is not clear how detecting binding of an antibody to the soluble polypeptide will detect binding of a chemical compound to the soluble polypeptide.

In response, in an attempt to advance the prosecution of the subject application, but without conceding the correctness of the Examiner's position, applicants have canceled claim 208, thereby rendering this rejection moot.

b. The Examiner rejected claim 213 under 35 U.S.C. §112, second paragraph, as similarly vague and indefinite, because it is

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dependent on claim 226, which is a competitive binding assay for determining whether a chemical compound specifically binds to a soluble polypeptide, and the detection method in claim 213 comprises detecting binding of an antibody to the soluble polypeptide. The Examiner alleged that it is not clear how detecting binding of an antibody to the soluble polypeptide will detect binding of a chemical compound to the soluble polypeptide, unless the antibody is the second chemical compound which should be stated in the claim.

In response, in an attempt to advance the prosecution of the subject application, but without conceding the correctness of the Examiner's position, applicants have canceled claim 213, thereby rendering this rejection moot.

c. On page 5 of the November 6, 2001 Office Action, the Examiner rejected claims 213, 214, 226 and 227 as allegedly indefinite because claim 226 encompasses a binding assay, but as written, the first step of the assay could be interpreted as separately contacting the soluble polypeptide with the first and the second chemical compound. The Examiner then suggested that the word "separately" on the 21<sup>st</sup> line be replaced with the word "first", and inserting the word "separately" in between "and" and "with only" on the 24<sup>th</sup> line of claim 226.

In response, in an attempt to advance the prosecution of the subject application, but without conceding the correctness of the Examiner's position, applicants have amended claim 226 to change the location of the word "separately" as suggested by the Examiner.

Applicants maintain that the amendments to claim 226 render the claim clear. Accordingly, applicants respectfully request that

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this rejection be withdrawn.

d. The Examiner also rejected claims 222 and 223 as allegedly indefinite because of the word "novel" in claim 222. The Examiner alleged that it is not clear what chemical compound would be novel and what wouldn't be novel.

In response, in an attempt to advance the prosecution of the subject application, but without conceding the correctness of the Examiner's position, applicants have amended claim 222 so that the claim does not recite the word "novel". Applicants note that claim 223 is dependent on claim 222.

Accordingly, in view of the amendment and remarks made hereinabove, applicants respectfully request that this ground of rejection be withdrawn.

Rejection under 35 U.S.C. § 102(b)

On page 5 of the November 6, 2001 Office Action the Examiner rejected claims 222 and 223 under 35 U.S.C. § 102(b) as allegedly being anticipated by any one of Jackson et al., Verploegen et al. and Grasso et al. publications cited in the previous Office Action, Paper No. 11. The Examiner alleged that compositions of the prior art meet the limitations of this claim.

In response, in an attempt to advance the prosecution of the subject application, but without conceding the correctness of the Examiner's position, applicants have amended claim 222. Applicants note that claim 223 is dependent on claim 222. Claim 222, as amended, now recites:

A method of obtaining a composition which comprises:

- (a) identifying a chemical compound by the

process of any of claims 224, 209, 225, 226, 214 or 227, or a structural and functional analog or homolog thereof,

- (b) recovering said chemical compound free of any soluble polypeptide, and
- (c) admixing a carrier and a pharmaceutically effective amount of said chemical compound.

Applicants note that the method of claim 222 requires first identifying a compound by the process of any of the recited claims. Applicants maintain that the prior art does not meet this first essential step of claim 222. Applicants further maintain that since the claims recited in claim 222 (namely, claims 224, 209, 225, 226, 214 and 227) are not anticipated by the prior art, then neither is the method of claim 222.

Accordingly, in view of the amendments and remarks made hereinabove, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

**Rejection under 35 U.S.C. § 103(a)**

On page 6 of the November 6, 2001 Office Action the Examiner rejected claims 208, 209, 213, 214, 218-220 and 224-228 under 35 U.S.C. § 103(a) as unpatentable over any one of Jackson et al., Verploegen et al. and Grasso et al. publications as cited in the previous Office Action, Paper No. 11 and above, in view of applicants' assertion on the record that the subject matter of these claims are obvious over the subject matter of claims 222 and 223.

In response, in an attempt to advance the prosecution of the subject application, but without conceding the correctness of the

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Examiner's position, applicants have canceled claims 208 and 213 and amended claim 222 as indicated hereinabove. Applicants maintain that amended claim 222 is directed to patentable subject matter.

Accordingly, in view of the amendments and remarks made hereinabove, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

**Advisory Information**

On page 7 of the November 6, 2002 Office Action, the Examiner noted the use of the trademark "FLAG". Applicants have amended that specification, as well as claims 224, 226 and 228 to capitalize the trademark "FLAG" and to include the "®" symbol. Applicants maintain that a FLAG epitope is well known in the art, as evidenced by its commercial availability as disclosed on page 62, line 21, and requires no further generic terminology.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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No fee, other than the enclosed \$110.00 fee for a one month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if an additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

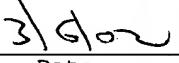
Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

   
3/16/98 Date

Alan D. Miller	Date
Reg. No. 42,889	